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| APPLI | CATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------|-------------|----------------------|---------------------|------------------|
| 10 | /733,172 | 12/11/2003 | Robert A. Janssen | SSK-51 (19354) | 5946 |
| DORITY & MANNING, P.A. POST OFFICE BOX 1449 | | | | EXAMINER | |
| | | | | MARCETICH, ADAM M. | |
| GREENVILLE, SC 29602-1449 | | | | ART UNIT | PAPER NUMBER |
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| | | | • | MAIL DATE | DELIVERY MODE |
| | | | | 05/24/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | • | Application No. | Applicant(s) | | | |
|--|---|--|--------------------------------|--|--|--|
| | | 10/733,172 | JANSSEN ET AL. | | | |
| | Office Action Summary | Examiner | Art Unit | | | |
| | | Adam Marcetich | 3761 | | | |
| Period fo | The MAILING DATE of this communication app r Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) filed on <u>02 A</u> | pril 2007. | | | | |
| · — | • | action is non-final. | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4) | Claim(s) 1-41 is/are pending in the application | • | | | | |
| | 4a) Of the above claim(s) <u>16-41</u> is/are withdrawn from consideration. | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | |
| 6)⊠ | Claim(s) <u>1-15</u> is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8) | Claim(s) are subject to restriction and/o | r election requirement. | | | | |
| Applicati | on Papers | | | | | |
| 9) 🗌 | The specification is objected to by the Examine | er. | | | | |
| 10)🛛 | The drawing(s) filed on <u>10 May 2007</u> is/are: a) | □ accepted or b) □ objected to be | by the Examiner. | | | |
| | Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | |
| | Replacement drawing sheet(s) including the correct | tion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) Notic3) Information | t(s) Le of References Cited (PTO-892) Le of Draftsperson's Patent Drawing Review (PTO-948) Le nation Disclosure Statement(s) (PTO/SB/08) Le no(s)/Mail Date See Continuation Sheet. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :18 June 2004, 8 November 2004, 15 February 2006.

DETAILED ACTION

Election/Restrictions

Claims 16-41 are withdrawn from further consideration pursuant to 37 CFR
 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or

linking claim. Election was made without traverse in the reply filed on 2 April 2007.

2. The election requirement mailed on 1 March 2007 has been withdrawn.

Information Disclosure Statement

3. The information disclosure statement filed 18 June 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The number "0118837" referring to US Patent Application Publication No. 0118837 to Modha et al. appears to be incorrect.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is

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required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The language "material to the patentability" should be changed to "material to patentability."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-4, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stockum (US Patent 4,853,978).
- Regarding claim 1, Stockum discloses an elastomeric glove comprising a substrate made of elastomeric material, an inner and outer surface and a coating overlaying the inner surface (column 1, lines 44-51). Stockum discloses examples of the coating comprising a crosslinked hydrogel network (column 3, lines 3-8, "cross-linked cornstarch" and column 4, lines 4-22, "carboxylated styrene butadiene lattices" in lines 18-19). Copolymers having an abundance of hydrophilic groups are capable of forming hydrogels. Stockum further discloses an active agent, which is capable of benefiting the

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user and is releasable from the network when the coating is contacted with an aqueous environment (column 3, lines 3-8).

- 8. Regarding claims 2 and 3, Stockum discloses embodiments having a glove formed from natural rubber latex (column 4, line 58; column 5, lines 10 and 26-27).
- 9. Regarding claim 4, Stockum discloses forming the hydrogel layer from carboxylated butadiene acrylonitrile lattices (column 4, lines 8-19). The monomer acrylonitrile is substantially soluble in water at 7 g/100 mL at 20 °C (online encyclopedia).
- 10. Regarding claim 7, Stockum discloses forming a coating layer with carboxylated styrene butadiene lattices as discussed in paragraph 7 above. Due to their high molecular weight and large size, these polymers are substantially insoluble in water.
- 11. Regarding claim 11, Stockum discloses adding an anti-microbial to the hydrogel layer (column 4, lines 4-7). An anti-microbial agent is substantially a drug.
- 12. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter (European Patent EP 0 455 323 A2).
- 13. Regarding claim 1, Potter discloses an elastomeric glove comprising a substrate made of elastomeric material (rubber latex on p. 3, ls. 16-17), having a coating overlaying the inner surface (coating in hydrogel polymer solution, p. 3, ls. 19-24), the coating comprising a crosslinked hydrogel network (2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA) on p. 3, l. 21), and active agent (cetyl pyridinum chloride (CPC), p. 3, l. 24). Rubber gloves by nature have both inner and outer

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surfaces. The agent is capable of imparting a benefit to the user and is releasable from the network when the coating is contacted with an aqueous environment (inhibiting bacterial growth on skin, p. 3, ls. 5-8).

- 14. Regarding claim 4, Potter discloses the use of 2-hydroxyethyl methacrylate (HEMA) in the coating as discussed in paragraph 13 above. The monomer of HEMA has a hydroxyl group and is always and necessarily hydrophilic and water-soluble.
- 15. Regarding claims 5 and 6, Potter discloses the use of 2-hydroxyethyl methacrylate (HEMA) as discussed in paragraph 13 above.

Claim Rejections - 35 USC § 103

- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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- 18. Claims 8-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockum.
- 19. Regarding claims 8-10, Stockum discloses a crosslinked hydrogel comprising carboxylated styrene butadiene lattices as discussed in paragraph 7 above. The property of hydrogel water content is dependent on the relative number of carboxyl groups in the hydrogel, making it a result-effective variable, subject to experimentation and testing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the relative number of carboxyl groups in order to form a hydrogel capable of retaining an appropriate amount of water away from a wearer's skin. See MPEP 2144.05(II)(A,B).
- 20. Regarding claim 15, Stockum discloses an absorbent article as discussed in paragraph 7 above. Stockum is silent with respect to the coating mass percentage applied to the gloves. The property of coating mass percentage is a result-effective variable, subject to experimentation and testing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the amount of coating applied to the glove in order to provide an acceptable amount of treatment material for the wearer. See MPEP 2144.05(II)(A,B).
- 21. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockum in view of Chou (US Patent 6,630,152).
- 22. Regarding claims 12 and 13, Stockum discloses an absorbent article as discussed in paragraph 7 above. Stockum lacks a skin conditioner and botanical agent.

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Chou discloses a skin conditioner coating the inner surface of a glove, in the form of Aloe Vera (column 2, lines 9-13 and column 3, lines 24-27). Aloe Vera is a botanical agent. Chou solves the problem of providing a skin treatment for the wearer of a glove, which is releasable in an aqueous environment (column 3, lines 62-64). Chou further discloses a need for low-cost disposable gloves able to deliver moisturizing or therapeutic substances without a greasy feel (column 2, lines 3-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Stockum as discussed with the Aloe Vera of Chou in order to condition skin without leaving a greasy feel. Additionally, Aloe Vera provides a lowcost moisturizer.

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23. Regarding claim 14, Stockum discloses an absorbent article as discussed in paragraph 7 above. Stockum is silent with respect to the coating thickness. Chou discloses a coating of about 0.01 mm, or 10 µm in thickness (column 4, lines 2-4). Chou demonstrates this value as being effective for providing a useful amount of treatment material to the wearer. The property of coating thickness is a result-effective variable, subject to experimentation and testing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the coating thickness in order to provide an acceptable amount of treatment material for the wearer. See MPEP 2144.05(II)(A,B).

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 25. Claims 1 and 11-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-12 and 16-18 of U.S. Patent No. 7,175,895 to Janssen. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:
- Regarding claim 1, Janssen discloses an elastomeric glove (claim 16, line 1), comprising a substrate made of elastomeric material (claim 16, lines 1-2), having an inner and outer surface (claim 16, lines 2-3), a coating overlaying the inner surface (claim 16, lines 2-3), the coating comprising a hydrogel network (claim 18, lines 1-2), and active agent (claim 17, lines 1-2). Hydrogels are by nature cross-linked, since they are formed from networks of polymer chains (online encyclopedia). The agent is capable of imparting a benefit to the user and is releasable from the network when the

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coating is contacted with an aqueous environment (claim 1, lines 1-2 and claim 12, lines 1-2).

- 27. Regarding claim 11, Janssen discloses a drug (claim 9, line 2).
- 28. Regarding claim 12, Janssen discloses a skin conditioner (claim 10).
- 29. Regarding claim 13, Janssen discloses aloe, a botanical substance (claim 11, line 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:30pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich

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Examiner Art Unit 3761

AMM 5/11/07

TATYANA ZALUKAEVA SUPERVISORY PRIMARY EXAMINER